June 14, 2022

Canon Inc.
% Mr. Gregory Woodard
Biomedical Engineer
Ken Block Consulting, LLC
800 East Campbell Road, Suite 202
RICHARDSON TX 75081

Re: K221620
Trade/Device Name: Digital Radiography CXDI-Elite, Digital Radiography E1
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: June 2, 2022
Received: June 3, 2022

Dear Mr. Woodard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: Division of Radiological Imaging
and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221620

Device Name
DIGITAL RADIOGRAPHY CXDI-Elite
DIGITAL RADIOGRAPHY EI

Indications for Use *(Describe)*
The DIGITAL RADIOGRAPHY CXDI-Elite / EI provides digital image capture for conventional film/screen radiographic examinations. This device is intended to capture, for display, radiographic images of human anatomy, and to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Applicant/ Sponsor:	Canon Inc. 9-1 Imaikami-cho Nakahara-ku, Kanagawa 211-8501 JAPAN
Contact Person:	Mr. Akira Hirai General Manager TEL: 81-3-3758-2111 FAX: 044-739-6695 hirai.akira@mail.canon

Date Prepared: June 10, 2022

Proposed Device	Manufacturer:	Canon Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-Elite DIGITAL RADIOGRAPHY E1
	Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Name:	Stationary X-ray System
	Product Code:	MQB
	Regulation:	892.1680, Stationary X-ray System
Predicate Device:	Clearance:	K213780
	Manufacturer:	Canon Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-Elite DIGITAL RADIOGRAPHY E1
	Common Name:	Solid State X-ray Imager (Flat Panel/Digital Imager)
	Classification Name:	Stationary X-ray System
	Product Code:	MQB
	Regulation:	892.1680, Stationary X-ray System

Device Description:

The DIGITAL RADIOGRAPHY CXDI-Elite, also called the DIGITAL RADIOGRAPHY E1, (hereinafter referred to as CXDI-Elite) is a solid-state x-ray imager. The CXDI-Elite is a series of detectors, and in the predicate device consists of the CXDI-720C Wireless detector unit, also called the AR-E3543W detector. The detector intercepts x-ray photons, and the scintillator emits visible spectrum photons that illuminate an array of photodetectors that create electrical signals. After the electrical signals are generated, the signals are converted to digital values, and the images will be displayed on monitors. The digital value can be communicated to the operator console via a wired or wireless connection.

The subject of this Special 510(k) submission is a change to the CXDI-Elite to add new detectors, the CXDI-420C Wireless (also called AR-E4343W) and the CXDI-420C Fixed (also called AR-E4343S), to the CXDI-Elite series of detectors. In addition, a Detector Stand (DS-01) has also been added as a component to be used with both the CXDI-720C Wireless and CXDI-420C Wireless. Compatibility with the Power Box (PB-01), a CXDI-Pro component that was cleared under K220098 has also been added. The CXDI Control Software has been updated from V3.10.0.4 to V3.10.2.2 to fix some bugs, update the GPU driver, and add several minor functional changes. Together, these changes make up the CXDI-Elite.

Canon

510(k) SUMMARY

Indications for Use:

The DIGITAL RADIOGRAPHY CXDI-Elite / E1 provides digital image capture for conventional film/screen radiographic examinations. This device is intended to capture, for display, radiographic images of human anatomy, and to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.

Summary of Technological Characteristics:

Comparison with the predicate device shows the technological characteristics of the CXDI-Elite is substantially equivalent to the predicate device. The flat panel detector units are functionally similar, but one of the proposed detectors, CXDI-420C Fixed, removes Standalone Mode as a photographing mode.

The major differences between the CXDI-Elite and the predicate are differences in standard and optional components, newer version of CXDI control software, difference in case material, and a photographing mode not available in the predicate device. The proposed indications for use statement is identical to the predicate device.

	Proposed Device	**Predicate Device**	
Trade Name	DIGITAL RADIOGRAPHY CXDI-Elite / E1	DIGITAL RADIOGRAPHY CXDI-Elite / E1	
510(k) Submitter [Number]	Canon Inc. [TBD]	Canon Inc. [K213780]	IDENTICAL
Indication for Use	The DIGITAL RADIOGRAPHY CXDI-Elite / E1 provides digital image capture for conventional film/screen radiographic examinations. This device is intended to capture, for display, radiographic images of human anatomy, and to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.	The DIGITAL RADIOGRAPHY CXDI-Elite / E1 provides digital image capture for conventional film/screen radiographic examinations. This device is intended to capture, for display, radiographic images of human anatomy, and to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.	IDENTICAL
Application	General Radiography	General Radiography	IDENTICAL
Components	CXDI-720C Wireless and CXDI-420C Wireless: Detector (Sensor) Battery Pack (LB-4A) Battery Charger (BC-01/BC-1A) Multi Box (MB-02) Status Indicator (SI-01/SI-4A) Wiring Cable (WC-01) PC Connection Cable (CP-01) Ready Indicator (RI-3A) X-ray Interface Box (XB-1A) Detector Stand (DS-01) CXDI-420C Fixed: Detector (Sensor) Multi Box (MB-02) Status Indicator (SI-01/SI-4A) Ready Indicator (RI-3A) X-ray Interface Box (XB-1A)	Detector (Sensor) Battery Pack (LB-4A) Battery Charger (BC-01/BC-1A) Multi Box (MB-02) Status Indicator (SI-01/SI-4A) Wiring Cable (WC-01) PC Connection Cable (CP-01) Ready Indicator (RI-3A) X-ray Interface Box (XB-1A)	MODIFIED
Other Compatible Components	Power Box (PB-01)	N/A	MODIFIED
Software	CXDI Control Software V3.10	CXDI Control Software V3.10	MODIFIED
Detector	CXDI-720C Wireless (AR-E3543W) CXDI-420C Wireless (AR-E4343W) CXDI-420C Fixed (AR-E4343S)	CXDI-720C Wireless (AR-E3543W)	MODIFIED

Pixel Pitch	125µm	125µm	IDENTICAL
Scintillator	CsI(Tl) [Cesium Iodide doped with Thallium]	CsI(Tl) [Cesium Iodide doped with Thallium]	IDENTICAL
Spatial Resolution	45% [MTF@2lp/mm]	45% [MTF@2lp/mm]	IDENTICAL
DQE	67% [@0.5 lp/mm, 3.5 uGy]	67% [@0.5 lp/mm, 3.5 uGy]	IDENTICAL
IP Level	CXDI-720C Wireless: IP57 CXDI-420C Wireless: IP57 CXDI-420C Fixed: N/A	IP57	MODIFIED
Wireless Communication	IEEE 802.11a/b/g/n/ac 2.4GHz/5GHz Bluetooth Low Energy (only for CXDI-720C Wireless and CXDI-420C Wireless)	IEEE 802.11a/b/g/n/ac 2.4GHz/5GHz Bluetooth Low Energy	IDENTICAL
External Dimensions	CXDI-720C Wireless: 384 x 460 x 15.5 mm CXDI-420C Wireless: 460 x 460 x 15.5 mm CXDI-420C Fixed: 460 x 460 x 15.3 mm	384 x 460 x 15.5 mm	MODIFIED
Photographing Mode	Standard Synchronization Mode, Standard Synchronization Mode with Built in AEC Assistance, Non Generator Connection Mode, Standalone Mode (only for CXDI-720C Wireless and CXDI-420C Wireless)	Standard Synchronization Mode, Standard Synchronization Mode with Built in AEC Assistance, Non Generator Connection Mode, Standalone Mode	MODIFIED

Summary of Non-Clinical / Test Data:

The fundamental scientific technology of the CXDI-Elite has not been modified. The changes are the addition of new detectors CXDI-420C Wireless (AR-E4343W) and CXDI-420C Fixed (AR-E4343S); the addition of an optional accessory, the Detector Stand (DS-01); the update to the CXDI Control Software from 3.10.0.4 to 3.10.2.2; and the update to the detector firmware from 02.00.00.03 to F2.00.03.00.

Evaluation of the addition of the new detector and optional accessories confirmed that the changes did not impact CXDI-Elite conformance with the U.S. Performance Standard for radiographic equipment and with relevant voluntary safety standards for Electrical safety and Electromagnetic Compatibility testing, specifically IEC standards 60601-1, 60601-1-2, 60601-2-54, and 60601-1-6.

These verification/validation activities successfully demonstrated that the device continues to meet the standards for the areas impacted by the modifications to the predicate device and raises no new questions regarding either safety or effectiveness when compared to the predicate device. Clinical testing is not necessary for the current submission, based on the minor differences from the predicate device. Adequate detector bench testing should be sufficient to demonstrate that the subject detector CXDI-Elite / E1 works as intended. Therefore, the verification/validation activities conducted support a determination of substantial equivalence for the CXDI-Elite.

The proposed device follows the applicable elements of the following FDA guidance documents: Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices, Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Radio Frequency Wireless Technology in Medical Devices, and Pediatric Information for X-ray Imaging Device Premarket Notifications.

Conclusion:

Canon Inc. considers the DIGITAL RADIOGRAPHY CXDI-Elite / E1 device to be substantially equivalent to the predicate device listed above. This conclusion is based on

the similarities in primary intended use, principles of operation, functional design, and established medical use.